

<b>Case Number:</b>	CM14-0008068		
<b>Date Assigned:</b>	02/12/2014	<b>Date of Injury:</b>	05/16/2009
<b>Decision Date:</b>	07/09/2014	<b>UR Denial Date:</b>	12/24/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/21/2014

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 39-year-old male with an injury reported on 05/16/2009. The mechanism of injury was not provided within the clinical notes. The clinical note dated 12/16/2013, reported that the injured worker complained of severe lower back pain. The clinical note dated 03/27/2014, reported that Lyrica had reduced 75% of the injured worker's neuropathic pain. The physical examination was not provided in the clinical notes. The injured worker's prescribed medication list included clonazepam 1 mg 3 times a day, Flurflex ointment, Opana 40 mg 3 times daily, Opana (IR) immediate release 10 mg as needed every 8 hours, Lyrica 150 mg 3 times daily, Pennsaid 1.5% 4 times daily and Ketofen Mild topical 3 times daily. The injured worker's diagnoses included status post motor vehicle accident (not involving another motor vehicle) with subsequent explosion and fire; burn (70% to 79% of body surface); chronic pain syndrome; prescription narcotic dependence; chronic pain-related insomnia; chronic pain-related anxiety; and chronic pain-related depression. The provider requested Opana 40 mg, Pennsaid 1.5% and Ketofen Mild. The rationale was not provided in the clinical note. The Request for Authorization was submitted on 12/31/2013. The injured worker's prior treatments were not provided in the clinical note.

### IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

**1 PRESCRIPTION OF OPANA 40MG #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines OPIOIDS.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list; Opioids, dosing; and Opioids, criteria for use Page(s): 93; 86; 78.

**Decision rationale:** The request for 1 prescription of Opana 40 mg (Quantity: 90.00) is non-certified. The injured worker complained of severe low back pain. The injured worker's prescribed medication list included Opana 40 mg 3 times daily and Opana IR (immediate release) 10 mg every 8 hours as needed. The treating physician's rationale was not provided. The California MTUS Guidelines recognize Opana (Oxymorphone) as an opioid. The guidelines recommend that dosing not exceed 120 mg oral morphine equivalents per day; and for patients taking more than one opioid, the morphine equivalent doses of the different opioids must be added together to determine the cumulative dose. The guidelines recognize four domains that have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. There is a lack of clinical information provided documenting the efficacy of Opana as evidenced by decreased pain significant objective functional improvements. The requesting provider did not specify the utilization frequency of the medication being requested. Moreover, Opana 40 mg a day at 3 times daily equals a total of 360 mg morphine equivalent dosage. Also, in combination with Opana IR with a maximum as needed dose of 30 mg additional, the total daily morphine equivalent dosage equals 450. This is a value greater than the 120 mg of morphine equivalent dosage recommended by the guidelines. As such, the request is non-certified.

### **1 PRESCRIPTION OF PENNSAID 1.5% 150ML: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL NSAID.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 112.

**Decision rationale:** The request for 1 prescription of Pennsaid 1.5% at 150 mL is non-certified. The injured worker complained of severe lower back pain. The treating physician's rationale was not provided within the clinical note. Pennsaid is topical diclofenac sodium. The CA MTUS Guidelines recognize Pennsaid as a non-steroidal anti-inflammatory drug. Topical application for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. There is a lack of clinical information provided documenting the efficacy of Pennsaid 1.5% as evidenced by a decrease in inflammatory pain and significant objective functional improvements. The requested provider did not specify the utilization frequency or the location of application of the medication being requested. Nonsteroidal anti-inflammatory drug topical ointments are not recommended for the treatment of the spine, hip or shoulder. As such, the request is non-certified.

**1 PRESCRIPTION OF KETOFEN MILD (CAPSAICIN, BACLOFEN, KETOPROFEN)  
0.0375%/5%/20% 240MG #1: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

**Decision rationale:** The request for 1 prescription of Ketofen Mild (capsaicin/baclofen/ketoprofen) 0.0375%/5%/20% at 240 mg (Quantity: 1.00) is non-certified. Ketofen Mild contains capsaicin 0.0375%, and the guidelines do not recognize that the additional 0.0125% formulation would provide any further efficacy. Moreover, Ketofen Mild contains baclofen 5%. The CA MTUS Guidelines recommend capsaicin only as an option in patients who have not responded or are intolerant to other treatments. Capsaicin is generally available as a 0.025% formulation and a 0.075% formulation. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. The guidelines do not recommend topical baclofen, and compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend topical baclofen. The combination of baclofen and the dosage of capsaicin are not recommended by the guidelines. The guidelines state that if the product contains at least 1 drug that is not recommended, it is not recommended. Thus, the request is non-certified.